

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Brian A. Rosenfeld, M.D. and Michael Breslow, M.D.

Serial No.: 09/443,072 Group Art Unit: 2167

Filed: 11/18/99 Examiner: Harle, J.

**For: SYSTEM AND METHOD FOR PROVIDING CONTINUOUS, EXPERT
NETWORK CRITICAL CARE SERVICES FROM A REMOTE LOCATION(S)**

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AFFIDAVIT BY DR. Steven J. Corwin

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I, Dr. Steven Corwin, residing at 36 Aspen Way, Upper Saddle River, NJ 07458 state as follows:

1. I obtained my MD degree in Medicine in 1979 from Northwestern University.
2. My experience includes sixteen (16) years in Intensive Care Medicine at Columbia-Presbyterian Medical Center.
3. My Curriculum Vitae is attached to provide further information regarding my background and qualifications that allow me to make the statements contained herein.
4. I have read and reviewed Patent Application Serial No.: 09/443,072 and the attached amended claim set.
5. I have read and reviewed the attached article "Intensive care unit telemedicine: Alternate paradigm for providing continuous care" from *Critical Care Medicine* 2000 Vol. 28, No. 12 by Rosenfeld et al. (the "Rosenfeld Study") describing the clinical study for which Dr. Rosenfeld was the Principal Investigator. I am familiar with the procedures described in this paper.
6. I believe the claimed invention is materially different from the Rosenfeld Study for at least the following reasons:
 - The claimed invention provides centralized monitoring of a plurality of geographically disparate ICUs by intensivists. In contrast, the Rosenfeld Study monitored only

one single specialty 10-bed ICU. It is the capability of the claimed invention to allow a physician-led team made up of intensive care specialists, critical care nurses and clerical support personnel (care team), to care for patients in multiple ICU's in disparate geographic locations, either within a building or in different buildings, simultaneously that creates new efficiencies and offers the potential to change the care paradigm for ICU patients. Thus, the expertise of the care team is leveraged over many ICU patients, who could not otherwise (without the claimed invention) be cared for by a single team.

- In contrast to the Rosenfeld Study where a single intensivist monitored faxed information, or initiated communication to view a single patient's bedside monitor over a personal computer, the claimed invention uses a computerized patient care management system that feeds key clinical information on multiple ICU patients simultaneously to the remote monitoring care team. The claimed invention includes imbedded decision support algorithms that further assist the care team in the continuous monitoring of large numbers of ICU patients. The claimed invention analyzes simultaneously all incoming patient physiologic data (from the bedside monitors) and laboratory data and provides visual alarms for the care team that alert them to detrimental trends in patient vital signs and/or laboratory values that they might not otherwise be aware of. These features of the claimed invention allow a single physician-led team to care for patients in multiple, geographically disparate sites simultaneously. These features are totally lacking from the Rosenfeld Study and are not suggested by the study in any way.
- The claimed invention provides for 24-hour dedicated monitoring/management by a care team. The care team provides this service from a dedicated monitoring facility comprising equipment and decision support algorithms developed explicitly for this purpose. The claimed invention provides for automated warnings relating to vital signs and trends in vital signs, provides assessment of those trends for the intensivist, and makes recommendations for intervention available for consideration by the intensivist. The care team has no other care responsibilities during the time it is monitoring/managing the multiple geographically disparate ICU(s). The attention of the care team is devoted to the ICU patients and only the ICU patients.
- In contrast to the present invention, the Rosenfeld Study provided only 4-5 hours of ad hoc monitoring by a single intensivist from the intensivist's home (i.e. no continuous monitoring, no support personnel, and no dedicated facility). Further, the intensivist monitoring was not triggered in any automated way by any form of decision support algorithms, but was conducted periodically by the intensivist, as he deemed fit and time permitted. The intensivist in the Rosenfeld Study was solely responsible for analyzing the data, deducing trends in the patient's vital signs, assessing the meaning of the trends, and deciding on the corrective action to be taken – without access to any software tools to assist in these tasks. The software tools in the claimed invention create efficiencies that enable a single, intensivist-led team to monitor and care for large numbers of ICU patients.


7. I believe that remote, 24-hour intensivist-led care team monitoring of ICU patients in multiple geographically disparate locations is not taught by the Rosenfeld Study nor would one of skill in the art make the required changes to the equipment and procedures of the Rosenfeld Study to arrive at the present invention for at least the following reasons:

- Remote monitoring and direct intervention of ICU patients is contrary to prior accepted practice, where physicians are physically present in the ICU.
- The generally accepted medical monitoring paradigm in ICU's with intensivists on-staff is for the intensivists to conduct rounds with the staff, and for ICU nurses and other physicians to notify the intensivists of emergencies on an as-needed basis. The Rosenfeld Study subscribed to this generally accepted model of intensivist deployment in ICU's, daily rounds, periodic monitoring, and responding to requests for assistance from on-site personnel.
- The monitoring paradigm presently employed by hospitals is having lower-skilled bedside nurses perform this function. These personnel, with only bedside patient monitoring equipment and visual inspection, are relied on to make the decision to contact specialists, such as intensivists, when problems are detected.
- The invention described and claimed in Application Serial No.: 09/443,072 does not rely on the paradigm of primary monitoring by bedside personnel, with secondary calls to intensivists, but rather has the off-site intensivist-led care team provide continuous, 24-hour monitoring. The care team is capable of unilaterally entering the patient room for video and audio communication, is supported by decision support algorithms that automatically alert the intensivist to detrimental trends in patients' vital signs and facilitate the intensivist contacting the lower-skilled on-site personnel when interventions are necessary. Although the Rosenfeld Study included intensivist-initiated intervention through on-site physicians, the lack of 24-hour continuous monitoring illustrates that the prior art monitoring paradigm was still considered valid by those in the Rosenfeld Study.
- The Rosenfeld Study disclosed nothing of the technological nature disclosed in the claimed invention. Indeed the only way the intensivist had contact with the ICU and/or access patient data was for the intensivist to intermittently conduct activate dial-up direct monitoring of the real-time bedside waveforms, request information by fax machine, or to telephonically contact an ICU nurse and have equipment (such as a video camera) physically moved to the desired patient location. None of this activity was in response to any system of automated notification to the intensivist and most required actions by on-site personnel.
- The technology tools that were developed in the current invention, such a smart alarms and physiologic data trend analysis, instantly available video monitoring from permanent camera installations in each ICU room, and comprehensive data links to the command center, were not available at the time of the original clinical study nor was their use suggested in any way.

- The initial clinical study never addressed the potential for a single monitoring site for overseeing the care of patients in multiple ICU's, thereby leveraging the expertise of an intensivist over a number of ICU's in geographically disparate locations.
 - The original trial technology suite could not have been used over multiple ICU's in different geographic locations.
 - At the time of the clinical study it was unprecedented to have an intensivist functioning in a dedicated monitoring capacity and NOT attending to other functions.
 - During the Rosenfeld study, an intensivist was required to monitor, on an ad-hoc basis, over a 24-hour shift. Continuous monitoring over such a long time period is too physically and mentally taxing to be feasible. In contrast, the system of the current invention allows for constant monitoring by an intensivist-led care team functioning on a normal 6-12 hour shift thereby alleviating both the physical and mental stress associated with a 24-hour shift.
 - The Rosenfeld study was not the same model as that used in the present invention's model. The functioning of the current system constitutes an entirely different manner of monitoring multiple, geographically disparate ICU's than the clinical study which monitored but a single ICU without the analytical support offered in the present invention system.
 - For a variety of licensing and clinical reasons, the clinical study was not a feasible model for hospitals to use for ICU care. Individual hospitals would not have established intensivists at remote locations to monitor a single ICU at the hospital, having only the technology described in the study as a supporting infrastructure.
 - When compared to the prior standard of care, that is, an on-call intensivist responding to calls from on-site nurses, the results of using the present invention are remarkable, resulting in far better outcomes for ICU patients and far earlier intervention in life-threatening trends.
8. I believe that providing either a computerized patient care management system or a set of decision support algorithms to a remote care team (or a combination thereof) is not taught by the Rosenfeld Study, and neither the paper nor the standard practices of the time would suggest such a modification for at least the following reasons:
- The use of computerized patient care management systems at the time of the invention was limited, even in major hospitals, to the recording of patient data for later review by physicians, and to isolated on-site systems that sound an audible alarm when an extreme condition in a patient's vital signs is reached (i.e. cardiac arrest). Further, computerized decision support algorithms in the medical community were not available.

- When computerized patient care management systems are deployed by hospitals, they are provided at the bedside or ICU nursing stations. They are not provided remotely to a physician. Instead, physicians are contacted by a bedside nurse (via a "pager") to inform them that a problem has developed.
 - Since the accepted wisdom of the medical community is to deploy patient care management systems and/or paper-based decision support for lower-skilled medical care givers on-site, there would be no reason to deploy these systems at a remote site for a care giver having the higher-skills of an intensivist.
9. The Rosenfeld Study evaluated the potential of "currently available technology" to "extend the effective reach of intensivists," but failed to disclose or suggest any of the additional technology of the presently claimed invention, such as (i) intensivist access to patient care management systems and/or decision support algorithms, that are required to effectively scale the monitoring to a greater number of patients and (ii) central command center monitoring that is required to effect a viable remote ICU monitoring model, (iii) monitoring of a plurality of geographically disparate healthcare locations/ICUs from a single remote command center, (iv) the use of a care team to enable monitoring and intervention on multiple patients in geographically different locations and (v) a data server/data warehouse for storing and analyzing data.

Date: 10/24/02

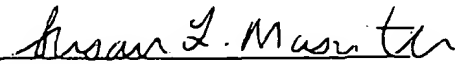

STEVEN J. CORWIN, M.D.
 Title Senior Vice President & Chief Medical Officer
 Affiliation NEW YORK-PRESBYTERIAN HOSPITAL

WITNESS MY HAND and seal this 24 day of October, 2002.

STEVEN J. CORWIN, M.D.
 Type Name Here

STATE OF NY)
) ss:
 COUNTY OF NY)

On this 24th day of October, 2002 personally appeared before me Steven J. Corwin to me known, and known by me to be the same person described in and who executed the foregoing instrument, and acknowledged that he executed the same, of his own free will and for the purposes set forth.


 Notary Public

My Commission Expires: 11-30-05

SUSAN L. MASCIPELLI
 NOTARY PUBLIC, State of New York
 No. 31-4846404
 Qualified in New York County
 Commission Expires Nov. 30, 2005

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Atty. Docket No. 2484-001

**STEVEN J. CORWIN, M. D.
CURRICULUM VITAE**

PERSONAL

Date of Birth: January 8, 1956
Place of Birth: White Plains, New York
Spouse: Ellen Corwin, R.N.
Children: Joseph, age 15 and Catherine, age 13
Social Security #: 117-48-6313
Citizenship: USA

Home Address:
36 Aspen Way
Upper Saddle River, NJ 07458

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New York-Presbyterian Hospital
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Room Payson 114
New York, NY 10021
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Current Position: Senior Vice President and Chief Medical Officer
New York-Presbyterian Hospital

EDUCATION Northwestern University
(Six Year Honors Medical Program)

1973 - 1977 BS - Northwestern University
Division of Arts and Sciences
Evanston, Illinois

1979 MD - Northwestern University
School of Medicine
Evanston, Illinois
GRADUATED SUMMA CUM LAUDE

TRAINING

1979 - 1982	Internship/Residency Department of Medicine Columbia-Presbyterian Medical Center New York, NY
1982-1983	Clinical Instructor in Medicine Columbia University College of Physicians and Surgeons
1982-1983	Chief Medical Resident, Department of Medicine Columbia-Presbyterian Medical Center New York, NY
1983 - 1986	Cardiology Fellow, Cardiology Division Department of Medicine Columbia-Presbyterian Medical Center New York, NY
1983-1986	Clinical Instructor in Medicine Columbia University College of Physicians and Surgeons

TEACHING APPOINTMENTS

1986 -1992	Faculty Internal Medicine Board Review Course
1992 -1995	Faculty Advanced Pathophysiology Elective 4th Yr. Medical Students
1986 – present	Medicine and Critical Care Attending Columbia Presbyterian Medical Center
2001 – present	Medicine Attending New York Weill Cornell Medical Center
2002 – present	Attending Physician in Cardiology New York Weill Cornell Medical Center

BOARD CERTIFICATIONS

1983	Board Certified. American Board of Internal Medicine
1986	Board Certified. American College of Cardiology

EMPLOYMENT

1999 – Present	NEW YORK-PRESBYTERIAN HOSPITAL Senior Vice President and Chief Medical Officer
1997 - 1999	MEDICAL DIRECTOR Columbia-Presbyterian Medical Center
1991 - 1997	DIRECTOR OF CRITICAL CARE SERVICES Columbia-Presbyterian Medical Center
1987 – Present	ATTENDING PHYSICIAN - CARDIOLOGIST Columbia-Presbyterian Medical Center
1986 - 1991	DIRECTOR OF CORONARY INTENSIVE CARE UNIT Columbia-Presbyterian Medical Center

ACADEMIC APPOINTMENTS

1986 -1998	ASSISTANT PROFESSOR OF CLINICAL MEDICINE Columbia College of Physicians and Surgeons
1998 – Present	ASSOCIATE PROFESSOR OF CLINICAL MEDICINE Columbia College of Physicians and Surgeons

LICENSURE	New York State - 149221-1
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HONORS

2000	Hope and Heroes Award Given by the Children's Hospital Fund for promoting excellence in Pediatric Oncology.
2001	VHA Award for Clinical Quality Given for the design and implementation of an Emergency Department chest pain diagnosis and treatment protocol.

ORGANIZATIONS, COMMITTEES AND SOCIETIES

American Medical Association	1991- Present
Fellow American College of Cardiology	1986 - Present
Fellow Society of Critical Care Medicine	1991 - Present
The New York Academy of Medicine – Fellow	2001
The Health Management Academy – Member	2001
University Health Consortium (UHC) – Medical Leadership Community -	2002

HOSPITAL COMMITTEES (New York-Presbyterian Hospital)

Member - Residency Selection Committee, Department of Medicine	1986 – 1994
Chairman - Critical Care Advisory Committee	1991 – present
Chairman - Emergency Room Task Force	1995
Chairman - Pediatric Critical Care Search Committee	1996
Chairman – Sentinel Events Committee	1998 – present
Member – Formulary & Therapeutics Committee	1998 – present
Member – Medical Board Executive Committee	1998 – present

Chairman – Information Technology Steering Committee 2001 – Present
Creating information technology plan for New
York-Presbyterian Hospital, Columbia
University College of Physicians and
Surgeons and Weill Cornell Medical College

Co-Chair of the Clinical Trials Advisory Committee 2000 - Present
Overseeing clinical research of Columbia Presbyterian
Medical Center and the Clinical Trials Network
sponsored by New York-Presbyterian Hospital,
Weill Cornell Medical College and Columbia University
College of Physicians and Surgeons

TRUSTEE COMMITTEES (New York-Presbyterian Hospital)

Executive Committee

Investment Committee

Finance and Audit Committee

Co-Chair – Hospital Quality Assurance Committee

UNIVERSITY COMMITTEES

Research Planning Committee
Columbia University College of Physicians and Surgeons

Hospital Representative on the Strategic Planning Committee for Clinical Care
Columbia University College of Physicians and Surgeons

Hospital Representative on the Cornell Physician Organization Strategic Planning Committee
Overseeing master facility and clinical care planning effort between New York –
Presbyterian Hospital and Weill Cornell Medical College

NEW YORK-PRESBYTERIAN HOSPITAL INSURANCE PROGRAM

Hospital representative Claims and Risk Management Committee for Medical Center Insurance Company – MCIC. Hospital insurance captive with Columbia University College of Physicians and Surgeons, Weill Cornell Medical College, John Hopkins, University of Rochester and Yale.

CITY AND STATE

**Greater New York Hospital Association Bioterrorism Committee
Greater New York Hospital Association Quality and Outcomes Committee**

PUBLICATIONS

ORIGINAL ARTICLES

- 1. Westenfelder G.O., Akey D.T., Corwin S.J., Vick W.A. Mycoplasma Pneumoniae and Acute Transverse Myelitis. Arch. Neuro. 38:317-19, 1981.**
- 2. * Corwin S.J., Reiffel J.A. Nitrate Therapy in Angina Pectoris. Arch. Internal Med. 145:538-43, 1985.**

SELECTED ABSTRACTS, PRESENTATIONS AND EXHIBITS

ABSTRACTS

- 1. * Corwin S.J., Horn E.M., Steinberg S.F., Neuberg G.W., Chow Y.K., Bilezikian J.P., and Powers E.R. The Effects of Angiotensin Converting Enzyme Inhibition on Components of the Beta Receptor System in Congestive Heart Failure. Circulation, Supp. II, 1237A, 1986.**
- 2. Horn E.M., Steinberg S.F., Chow Y.K., Neuberg G.W., Corwin S.J., Power E.R. and Bilezikian J.P. Altered Beta Adrenergic Receptors and Guanine Nucleotide Binding Regulatory Proteins in Congestive Heart Failure. Clin. Res. 34:857A, 1986.**
- 3. Lazar EJ, Sollano JA, Reich Cooper M, Corwin SJ, Schwartz A: Does hypertension affect outcome in acute myocardial infarction? Journal of the American Society of Hypertension 2001; 14(4): 201A**

4. **Sollano JA, Reich Cooper M, Corwin SJ, Cannavale PJ, Lazar EJ: Hospital volume matters: A risk adjusted volume-outcome analysis of in-hospital deaths in New York State following acute myocardial infarction. Circulation 200; 102 (18): 850-7**

In Preparation/In Submission:

Model for a Merger: The Role of Service Lines in a Merged Academic Medical Center. Corwin SJ, Cooper MR, Berman M.

Model for a Merger: Driving Integration Through Quality. Corwin SJ, Cooper MR, Johnson T, Berman M

Model for a Merger: Matrix Reporting and the CMO Role. Corwin SJ, Cooper MR, Berman M.

Creating a New Quality Model: An Academic Medical Center's Approach to Performance Improvement. Corwin SJ, Cooper MR, Johnson G, Berman M.

SSI: How Does an Academic Healthcare System Approach Quality? Lazar EJ, Berger L, Alpert J, Cooper MR, Corwin S, Callahan M, Heinrich G, Klein A, Berman M

Adjustment of Hypoglycemic Medications During NPO Periods: Impact of a Computerized Reminder. Oppenheim M, Eschle AM, Holdsworth D, Velasco F, Mintz R, Boyer A, Cooper MR, Corwin SJ, Cooke J.

Computerized Alerting Regarding Abnormal Trends in Laboratory Values: Impact on Physician Behavior. Oppenheim M, Lamarca C, Corwin SJ, Boyer A, Cooper MR.